**MARK W. HOWARD, M.D.**
**Orthopaedic Surgery**

**Specializing in Disorders and Deformities of the Spine**

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December 16, 1999

Document Management Branch
HFA-305 Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville MD 20852

RE: DOCKET #97N-484S

To Whom It May Concern:

This is a letter of objection in reference to the reported upcoming FDA plans to regulate some types of allograft, that is, medical devices.

In my orthopedic and spinal surgery and reconstructive practice, I use a lot of different allograft materials which are critically important as far a spinal fusion and reconstruction. If these are then forced to go through the scrutiny and processing required of medical devices, this will present a major hindrance to my ability to most adequately and appropriately take care of my patients with these advanced procedures, and in my opinion it's unnecessary and unreasonable.

I'd be certainly willing to further discuss this issue with anybody concerned with the matter directly. I would encourage your organization to not introduce any additional red tape or bureaucratic slow-down that would prevent my ability to utilize allograft implants, especially critical in spinal fusion reconstructive procedures.

Sincerely,

Mark W. Howard, M.D.
Diplomate, American Board of Orthopaedic Surgery

MH/kv

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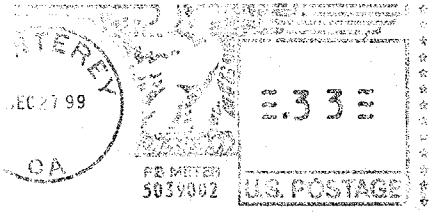


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